

AMERICAN FARM BUREAU FEDERATION®

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October 13, 1999

Dockets Management Branch HFA-305 Food and Drug Administration Rm. 1061 Rockville, MD 20852

RE: Docket No. 99N-2151, 21 CFR Part 514 (New Animal Drug Applications; Sheep as a Minor Species)

The American Farm Bureau is the largest general farm organization in the United States representing almost five million members. We represent producers in all of the major livestock sectors. We submit the following comments regarding "New Animal Drug Applications; Sheep as a Minor Species."

We strongly support the reclassification of sheep as a minor species with respect to all data requirements for new animal drug applications (NADA's). We support all efforts that will assist sheep producers and that also assure the safety and quality of sheep products. We believe that this step will accomplish both.

One of the major problems faced by sheep producers today is having access to animal drugs to assist them in keeping a healthy herd. Some of the more burdensome data collection requirements associated with a non-minor species have deterred drug companies from developing new drug applications for sheep. This has made it increasingly difficult for U.S. sheep producers to maintain healthy herds and thereby has made them less competitive in the world and domestic markets.

By reclassifying sheep as a minor species, costs of development will be reduced for companies seeking new drug applications for sheep. This in turn will provide sheep producers with more choices in treating their sheep, which may result in less resistance build-up of drugs available. This will result in a healthier, more competitive U.S. sheep industry.

Farm Bureau strongly supports science-based approaches to agriculture. And we feel that the agency has taken this approach in this matter. We urge the agency to issue a final rule reclassifying sheep as a minor species for all NADA collection requirements in an expeditious manner.

Sincerely,

Dean Kleckner

President

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